JUN 2 5 2001

K011181

510(k) SUMMARY

Submitted by:	ICS Medical 125 Commerce Drive Schaumburg, IL 60173 – 5329
Telephone:	(847) – 534 – 2150
Fax:	(847) – 534 – 2151
Contact Person:	Delmar F. Bloem, President
Date Summary Prepared:	June 1, 2001
Trade Name of Device:	ICS Medical CHARTR® OAE with TYMP
Common Name:	Otoacoustic Emissions Analyzer with Tympanometry System
Classification Name(s):	Audiometer and Auditory Impedance Tester
Classification:	Class II Medical device
Substantial Equivalence:	The CHARTR® OAE with TYMP is substantially equivalent to the Capella Device marketed by Madsen Electronics, Inc., located in Minnetonka, MN 55343. This company received 510(k) clearance for the Capella device (K002200). The OAE portion of the CHARTR® System is a product of ICS Medical, located in Schaumburg, IL 60173. The 510(k) clearance number for the CHARTR® OAE is K002985. In essence, this 510(k) summary is for the Madsen Tympanometry module built into the CHARTR® OAE Device.
Intended Use:	The ICS Medical CHARTR® OAE with TYMP System is indicated for the determination of cochlear function in infants, children and adults, which provides information about hearing sensitivity without subjective responses from the individual being tested. The Tymp module of the CHARTR® OAE with Tymp performs a check of the middle-ear function prior to performing OAE measurements.

Comparison of similarities and differences between ICS Medical CHARTR® OAE with Tymp and the Predicate device: Capella.

Please note only the items pertaining to the tympanometry are provided since the OAE portion of our product already received 510(k) clearance on December 13, 2000 (K002985).

	Capella (Tympanometry module) K002200	CHARTR® OAE wth TYMP (Tympanometry module)
Indication	Identical for Both	Products
Electrical Safety	EN 60601-1	EN 60601-1
EMC Compliance	Emission & Immunity: EN 6061-1-2	Same
Software	Both Use Most	Current Capella Software
Product Standard Compliance	Impedance: ANSI S3.39 and EN 61027	Same
Construction Type	PC-Based System	PC-Based System (Portable and Desktop PC versions)
Power Source	Mains and Battery (Rechargeable Battery)	Mains Only
Computer Interface	RS232 Communication	Same
Tympanometry	Probe is presented to the ear via the probe. The response reflects the acoustic immitance. Change of the acoustic immitance is registered as a function of air pressure in the external ear canal. Probe tone is controlled via SW and HW and is limited to max. output level 90 dB SPL. Air pressure is controlled via SW and HW and is limited to the range: +200 to –400 daPa.	
Probe Tip Material	Not specified	Silicone for Medical Applications.
Probe	Original Capella Probe	Hortmann Probe of Similar Design and Function.

Electrical Safety: This product is designed to meet EN 60601-1 standard for medical devices.

EMI Compatibility: This product is designed to meet EN 60601-1-2 standard.

Other Standards: Impedance: ANSI S3.39 and EN 61027

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ICS Medical Corporation
C/O Delmar F. Bloem, President
125 Commerce Drive
Schaumburg, IL 60173-5329

Re: K011181
Trade/Device Name: ICS Medical CHARTR® OAE with TYMP
Regulation Number: CFR# 874.1050 & CFR# 874.1090
Regulatory Class: Class II
Product Code: 77 EWO & 77 ETY
Dated: April 17, 2001
Received: April 18, 2001

Dear Mr. Bloem:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011181

Device Name: ICS Medical CHARTR® OAE with TYMP System

Indications For Use:

The ICS Medical CHARTR® OAE with TYMP System is indicated for the determination of cochlear function in infants, children and adults, which provides information about hearing sensitivity without subjective responses from the individual being tested.

The TYMP module of the CHARTR® OAE with TYMP performs a check of the middle-ear function prior to performing OAE measurements.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011181

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)